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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Michael S. Greenfield  
 McDonnell Boehnen Hulbert & Berghoff  
 32nd Floor  
 300 S. Wacker Drive  
 Chicago, IL 60606

EXAMINER

LUCAS, ZACHARIAH

ART UNIT PAPER NUMBER

1648

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/746,581	<b>Applicant(s)</b> JOURDIER ET AL.	
	<b>Examiner</b> Zachariah Lucas	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 6, 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Currently, claims 1-10 are pending in the application. In the prior action, mailed on November 4, 2003, claims 1-5, 8, and 9 were rejected, and claims 6 and 7 were withdrawn as to non-elected inventions. In the Response filed on February 4, 2004, the Applicant amended claims 1, 3-5, and 8, and added new claim 10. Currently, claims 1-5, and 8-10 are under consideration.

### ***Priority***

2. Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon an application filed in France on June 26, 1998. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said application, since the United States application was filed more than twelve months thereafter. It is noted that the Applicant has also claimed priority to PCT/FR99/01554. Although the filing date of this application would, if priority were claimed to the PCT under 35 U.S.C. 120, move the U.S. filing date back to June 28, 1999. However, the Applicant has claimed priority from this document under 35 U.S.C. 119, rather than under 35 U.S.C. 120. Thus, the filing date of the PCT application is not presently the earliest U.S. filing date of the present application. The Applicant is therefore not presently entitled to the priority date of the French application.

### ***Specification***

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3. **(Prior Objection- Withdrawn)** The disclosure was objected to because of the following informalities: On pages 15-16, it appears as though a portion of the disclosure, possibly the material later restated in the table on pages 17 and 18, is absent. In view of the amendment to the specification, the objection is withdrawn.

#### ***Claim Objections***

4. **(Prior Objection- Withdrawn)** Claims 5 and 8 were objected to because of the following informalities: the term “virus” is redundant as “HIV” stands for human immunodeficiency virus. In view of the amendment of the claims, the objection is withdrawn.

#### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. **(Prior Rejection- Withdrawn)** Claims 1-5, 8, and 9 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims were rejected because it was unclear if the claims were intended to read only on the induction of protective responses, or if the claims were intended to read on any immunogenic response. In view of the amendment of the claims such that they read on the induction of any immune response (i.e. by deletion of the term “vaccine”), the rejection is withdrawn.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. **(Prior Rejection- Withdrawn)** Claims 1-5, 8, and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of producing local immunogenic responses against HIV, does not reasonably provide enablement for embodiments wherein a protective response is being raised against HIV. In view of the amendment of the claims such that they no longer require the induction of a protective response, the rejection is withdrawn.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. **(Prior Rejection-Withdrawn)** Claims 1- 3, 5, 8, and 9 rejected under 35 U.S.C. 102(b) as being anticipated by Thibodeau et al., (C R Acad Sci, Paris 313: 389-94- of record in the IDS of March 2001). The claims read on the application of an HIV antigen to the floor of a mammals mouth in order to induce an immune response. Applicant's argument that the reference does not teach the application of the composition to the floor of the mouth is noted. The claims have been amended such that the claims now require that the mammal be a primate. In view of the amendment, the rejection is withdrawn.

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11. **(Prior Rejection- Withdrawn)** Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Gaffar et al. (U.S. Patent 3,931,398- submitted in the IDS of March 2001). In view of the amendments to the claims, and the arguments in traverse, the rejection is withdrawn.

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. **(New Rejection, necessitated by amendment)** Claims 1- 3, 5, and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thibodeau et al. (C R Acad Sci, Paris 313: 389-94- of record in the IDS of March 2001), in view of the teachings of Lowell et al. (the Lowell patent, U.S. Patent 5,985,284) and Heiber et al. (U.S. Patent 5,516,523). The teachings of Thibodeau were described in the prior action. As indicated, the reference teaches the oral administration to rodents of an immunogenic composition comprising the gp160 HIV antigen. While Thibodeau does not specifically teach the administration of the antigen to the floor of the mouth, the reference does teach the administration of a liquid formulation into the rodent's mouth. Thus, because the liquid would naturally go towards the bottom the mouth, the described

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method of administration would inherently involve the contacting of the floor of the mouth with the antigen formulation.

The claims have now been amended to read on the administration of the antigen formulation to the floor of a primate's mouth. In combination with the amendment, the Applicant argues that the reference does not teach the application of the composition to the floor of the mouth, and that the reference does not provide a reasonable expectation of success in such an administration in primates or humans. These arguments are not found persuasive.

This is because the sublingual mucosa is an route of oral vaccination known to those in the art. See e.g., the Lowell patent , column 4 lines 49-53. Further, it is also known in the art that the sublingual membrane is more permeable than other membranes in the oral cavity, making it an attractive target for oral administrations. See e.g., Heiber, column 1, lines 35-48. Thus, from the teachings of Thibodeau, in combination with those of Heiber and the Lowell patent, it would have been obvious to those in the art that administration of the gp160 antigen to the floor of the mouth would result in an immunogenic response against the antigen.

The Applicant argues that the present specification teaches that there are no grounds in the art for those to assume that Thibodeau's results in rodents would could be applied to humans. However, neither the specification nor the Applicant provides any support for this assertion. Further, in view of the teachings of the Lowell patent, indicating that sublingual administration of an immunogenic composition would be effective in humans, this unsupported statement lacks weight, particularly when the teachings of the Lowell patent are supported by those of the art generally. See e.g., Merino et al., GB 2110085; Fields et al., U.S. Patent 5,736,315, col. 10, lines 25-34); and Marchal et al., U.S. Patent 5,599,541, col. 3, lines 40-43 (each indicating that the

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administration of antigens via sublingual routes were expected by those in the art to be effective at inducing an immune response). For these reasons, the reformed rejection of claims 1- 3, 5, and 8-10 over the teachings of Thibodeau, Heiber, and the Lowell patent is maintained.

14. **(Prior Rejection- Reformed and maintained)** Claims 1-3, 5, 8 and 9 were rejected under 35 U.S.C. 103(a) as being unpatentable over Thibodeau as applied to claims 1-3, 5, 8, and 9 above, and further in view of Mathiowitz et al. (U.S. Patent 6,235,313) and Irwin et al. (WO 96/20731- of record in the March 2001 IDS). The claims have been amended such that the claims now read on methods of administering the compositions to the floor of the mouth in primates. The Applicant traverses the rejection for substantially the same reasons as indicated with respect to Thibodeau alone, and are addressed in the rejection over Thibodeau, Heiber, and the Lowell patent above. The present rejection is reformed such that claims 1-3, 5, 8, and 9 are now rejected over the teachings of Thibodeau, Heiber, and Lowell further in view of Mathiowitz and Irwin. The rejection is maintained, and extended to new claim 10, for the reasons indicated above.

15. **(Prior Rejection- Reformed and maintained)** Claims 1-5, 8 and 9 were rejected under 35 U.S.C. 103(a) as being unpatentable over Thibodeau as applied to claims 1-3, 5, 8, and 9 above, and further in view of either Lowell et al. (J Infect Dis 175: 292-301), or Gandhi et al. (Adv Drug Deliv Rev, 13: 43-74). The Applicant traverses the rejection for substantially the same reasons as indicated with respect to Thibodeau alone, and are addressed in the rejection over Thibodeau, Heiber, and Lowell above. The present rejection is reformed such that claims 1-



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3, 5, 8, and 9 are now rejected over the teachings of Thibodeau, Heiber, and the Lowell patent further in view of Mathiowitz and Irwin. The rejection is maintained, and extended to new claim 10, for the reasons indicated above.

16. **(Prior Rejection-Maintained)** Claims 1-5, 8, and 9 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hinkula et al. (Vaccine 15: 874-78- of record in the IDS of March 2001) in view of Irwin and Beckenkamp (HNO 33:196-203), and further in light of the teachings of Kozlowski et al. (Infect Immun 65(4): 1387-94), and Gorse et al. (Clin Diag Lab Immunol 3(6): 769-73). The Applicant traverses this rejection by arguing 1) that the Hinkula and “at least one secondary reference” teach away from the claimed invention, and 2) that the references fail to suggest the claimed methods.

The Applicant appears to be reading the failure of Hinkula to specifically teach the sublingual administration of the composition as a teaching away. However, the fact that the reference chose to use one route of administration over another without providing a rationale as to why such was done is not sufficient to establish a teaching away. The Federal Circuit has indicated that “a reference will teach away [from a claimed invention] if it suggests that the line of development flowing from the reference’s disclosure is unlikely to be productive of the result sought.” In re Gurley, 31 U.S. PQ 2d 1130, 1131 (1994). The failure of Hinkula to teach the use of the specific route of administration, without providing any teachings suggesting that such a route would be inoperative, does not rise to such a level of “teaching away.”

17. It is further assumed that the “at least one secondary reference” referred to by the Applicant is the Beckenkamp reference. However, as was noted in the prior action, Beckenkamp

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teaches “that floor of the mouth is not the most responsive region of the mouth, the reference does teach that the cells in this region will produce IgAs.” This also does not constitute a teaching away. See, In re Gurley, supra, at 1132 (stating “A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use.”). Rather than teaching away from the claimed invention, the references merely teach that other routes of administration may be more effective, but still indicates that such a route of administration is likely to be successful.

In view of the above, the Applicant’s arguments in traversal of the rejection are not found persuasive, and the rejection is therefore maintained, and extended to new claim 10.

18. **(Prior Rejection- Maintained)** Claims 1-5, 8, and 9 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Becker et al. (U.S. Patent 6,379,675) in view of Gorse and Beckenkamp. The claims have been described above. The Applicant traverses this rejection on the grounds that 1) the teaching of Hinkula is limited to mice and that those in the art would have had no reasonable expectation of success in using the indicated method with primates, and 2) that the Beckenkamp reference teaches away from the claimed method. Each of these arguments substantially restates the Applicant’s arguments presented above in reference to, respectively, the rejections over Thibodeau, Heiber, and the Lowell, and the rejection over Hinkula, Irwin, Beckenkamp, Kozlowski and Gorse. These arguments are not found persuasive for the same reasons as indicated with respect to the rejections above. The rejection is therefore maintained, and extended to new claim 10.

***Conclusion***

19. No claims are allowed.

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Z. Lucas  
Patent Examiner



4/19/04  
JAMES HOUSEL  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600